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| 09/879,480   | 06/12/2001  | Jack C. Whittier     | HrdMgmtCIP          | 6452             |
| 7590   | 03/03/2005  |                      | EXAMINER            |                  |
| Santangelo Law Offices, P.C.<br>Third Floor<br>125 South Howes<br>Fort Collins, CO 80521 |             |                      | MYERS, CARLA J      |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1634                |                  |

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 09/879,480             | WHITTIER ET AL.     |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Carla Myers            | 1634                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 15 December 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 28-43 and 45-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 28-43 and 45-50 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 15, 2004 has been entered.

### **Claim Rejections - 35 USC § 112**

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-43 and 45-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide basis for amended claims 28-43 and 45-50. Specifically, the specification does not provide basis for the concepts of methods of managing a plurality of nonhuman female mammals for increased economic and "biological efficiency" in a commercial environment wherein the methods comprise estimating an economic cost of inducing early puberty in female non-human

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mammals, estimating an economic gain of harvesting substantially all of said nonhuman female mammals, utilizing a time interval wherein the time interval results in a net economic gain and harvesting the nonhuman female mammals upon expiration of a time interval that results in net economic gain and net biological gain.

The specification as originally filed provides basis for the general concept of a method of managing nonhuman female mammals and in particular provides support for methods which comprise inducing early puberty in a female nonhuman mammal, fertilizing at least one egg in said mammal using a plurality of sex-sorted spermatozoa, producing offspring from said mammal, and harvesting the mammals following the birth of offspring. At pages 12-13, the specification discusses an Integrated Herd Management System (IS) that incorporates reproductive factors such as inducing early puberty, synchronizing estrous, use of sex sorted sperm, and early weaning of offspring. At page 4, the specification teaches that one aspect of the invention is to increase the percentage of female animals available to expand the herd using sex-sorted sperm. It is stated that integrating early-weaning, induction of early puberty and sexed-sorted semen into a single calf heifer system will increase the value of non-replacement heifers and increase profitability. Additionally, the specification (e.g., page 27 and 49) provides an economic analysis of the total income and expenditures recorded per year. Gross revenue/loss and net revenue/loss were calculated. These calculations took into consideration, for example, pregnancy rates, calf survival, feed costs, breeding costs, pasture lease costs, health costs and market price. The specification (page 32) states that "simulations were conducted to evaluate the effect of pregnancy rate and increased

calf survival on profitability." Additionally, the specification (beginning at page 43) teaches evaluating carcass characteristics. At page 12, the specification states that "(w)hile Figure 7 provides a specific time line for beef cattle embodiment of the herd management invention, it is understood that (it) is illustrative of the broad variety of species of mammal that can be managed in a similar fashion." However, the cost analysis provided in the specification was performed with respect to the management of bovine.

The teachings in the specification do not provide basis for the specific embodiments set forth in the present claims. The specification teaches estimating the economic costs of inducing early puberty and discusses certain health effects and fertilization effects associated with inducing early puberty. The specification also discusses estimating the economic gain of harvesting the mammals that were bred. The specification does not teach a method of managing female nonhuman mammals based on the concepts of estimating an economic cost of inducing early puberty in female non-human mammals, estimating an economic gain of harvesting substantially all of said nonhuman female mammals, utilizing a time interval wherein the time interval results in a net economic gain and harvesting the nonhuman female mammals upon expiration of a time interval that results in net economic gain and net biological gain. As a whole, there is no disclosure in the specification or in the originally filed claims of a method of managing animals which takes into consideration only the cost of inducing puberty and the economic gain of harvesting animals. There is also no disclosure in the specification of a method of managing mammals which determines a time interval that

allows for a net economic gain wherein the time interval is determined based on the cost of inducing puberty and the economic gain of harvesting mammals and wherein the time interval is then used to determine when the mammals will be harvested. The specification teaches the use of estimates of economic cost and gain to evaluate the integrated herd management system – a system which is based on multiple parameters outside of inducing puberty and the time point of harvesting mammals. There are no teachings in the specification as to how to use the estimates of economic cost and gain for any purpose other than the integrated herd management system. The specification teaches the concept of the time interval between inducing early puberty and harvesting the mammals used for breeding (see, e.g., Figure 7). However, the specification does not teach the specific embodiment of determining a time interval that begins at inducing early puberty and ends at harvesting the mammal used for breeding, wherein the time interval results in a net economic gain and does not teach the step of harvesting the female mammals upon the expiration of this time interval. The teachings in the specification of specific time intervals between inducing early puberty and harvesting were not determined based on a time interval that results in a net economic gain. Also, the specification does not teach applying these specific teachings of the determining a time interval based on net economic gain to all traditionally herd-managed female mammals. The specification as originally filed does not specifically refer to "biological efficiency." While some of the parameters discussed in the specification may fall into the category of "biological efficiency," this category encompasses numerous parameters which are not discussed or analyzed in the present specification. It is noted that the

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claims have been amended to recite methods for managing traditionally herd-managed female mammals and specific claims are limited to methods in which the mammal is a bovine and equine. However, the examples provided in the specification are limited to the biological attributes of bovine. There are no clear teachings in the specification as to what is intended to be encompassed by the phrase "biological efficiency" with respect to equine and all other "traditionally herd-managed female mammals." The replacement system set forth in the specification is described with respect to its application to bovine. It is unclear as to how this replacement system similarly applies directly to mammals that are not bred as a food source. While the specification states at page 12, that the system is applicable to a variety of species of mammal "that can be managed in a similar fashion," animals such as equine are not typically managed in a system in which the animal that was just bred is replaced with its offspring. Similarly, while elephants, antelope, zebra etc are considered to be herd animals, it is not conventional to manage these other mammals in a system in which each time the mammal gives birth to an offspring, that mammal is slaughtered. The specification does not describe how one evaluates the biological efficiency of harvesting such mammals. Accordingly, the specification does not provide basis for the broadly claimed concept of estimating biological cost or biological gain of managing any female mammal for increased biological efficiency and does not provide basis for the concept of determining a time interval based on a net biological gain and then harvesting the mammal upon the expiration of the time interval.

Further, in the response of December 15, 2004, the claims were amended to recite that the mammal is a “nonhuman traditionally herd-managed female mammal.” The specification as originally filed does not appear to provide support for applying the herd management method to this particular subgenus of mammals. The specification does not define what constitutes the subgenus of “traditionally herd-managed female mammals.” There is no reference in the specification as originally filed to this subpopulation of mammals and it is unclear as to what would constitute “traditionally herd-managed female mammals.” The specification at page 6 states that the technologies described therein “have various applications with respect to a variety of species of mammal including, but not limited to, humans, bovids, equids, ovids, canids, felids, goats, as well as less commonly known animals such as elephants, zebra, camels, or kudu.” However, the teachings in the specification of a genus of mammals and of particular species of mammals does not provide basis for the distinct concept of a subgenus of mammals that consists of “traditionally herd-managed female mammals.” “traditionally herd-managed female mammals.”

**RESPONSE TO ARGUMENTS:**

In the response filed December 15, 2004, Applicants traverse this rejection by stating that it is clear from the specification that “a time interval is affirmatively set in order to promote the economic sustainability of the SCH system.” Applicants assert that the specification discusses the effect of breeding by 9-months of age, the benefit of obtaining carcasses of high quality, and the desire to not sacrifice the quality of the progeny. Applicants conclude that “(i)n this manner, it is seen that the puberty induction

component of a time interval is affirmatively determined to result in a net economic gain." Applicants also point to page 12 as teaching that weaning may be accomplished to shorten the time interval between birth and harvest while allow for one parturition for replacement.

Applicants arguments have been fully considered but are not persuasive to overcome the present grounds of rejection. Applicants have pointed to individual teachings in the specification as providing support for the claims. However, the individual teachings do not provide support for the claims as a whole. The teaching that it is beneficial to harvest a mammal at 24 months of age and that to do so could be accomplished by breeding the mammal at 9 months of age does not lead one to conclude that the specification as originally filed intended to claim a method of managing mammals based solely on the analysis of the economic cost of inducing puberty and the economic gain of harvesting mammals. Throughout the specification numerous other parameters are evaluated as to their effect on economic gain and cost and these parameters are also taken into consideration in context with the cost and effect of the parameters of sex-sorting sperm and using sex-sorted sperm for artificial insemination. However, the claims do not recite that the management system takes each of these parameters and economic costs and gains into consideration. Further, the individual teachings of inducing puberty and obtaining an economic gain by harvesting mammals at an age to produce a high quality carcass does not provide support for the concept of a herd management method based on generating and utilizing a time interval in which the interval begins at the time of inducing puberty and ends at harvesting the

mammals and results in a net economic gain and based on the time interval, the mammals are harvested at the expiration of the time interval. Applicants arguments rely on individual teachings that are presented at various locations in the specification. However, the specification does not teach as a single embodiment the claimed methods and does not provide support for the concept of methods in which these concepts are brought together alone or in combination with other concepts and limitations to arrive at the presently claimed methods for managing nonhuman traditionally herd-managed female mammals. Basis for the claimed invention cannot be found by picking and choosing among the various concepts set forth in the specification and then combining these concepts in a manner which was not originally set forth in the specification (i.e., to generate a herd management system for increasing economic and biological efficiency based on an economic analysis of only the cost of inducing early puberty, the economic gain of harvesting mammals, by selecting a time interval for inducing early puberty and harvesting mammals that results in a net economic gain and harvesting mammals at the expiration of said time interval).

The response states that the specification uses the term "biological efficiency" at page 2 and thereby "any new matter concerns as applied to the term 'biological efficiency' are not warranted." However, the rejection is not premised on the fact that the phrase "biological efficiency" is or is not previously used in the specification. Rather, the rejection is based on the fact that the specification as originally filed does not provide support for the claimed methods of managing nonhuman traditionally herd-managed female mammals for increased economic and biological efficiency in a

commercial environment. Page 2 of the specification states "it has been hypothesized that the younger the cow herd, the greater proportion of total feed used for weight production and a smaller amount of feed used for maintenance, lactation, gestation, and body condition score, hence increased biological efficiency." It is not clear from this passage as to whether biological efficiency is evaluated on the basis of body condition score alone or is related to maintenance, lactation, gestation and body condition score. In either event, this passage does not teach or state that the specification intends to disclose a method of managing nonhuman traditionally herd-managed female mammals for biological efficiency by estimating economic cost of inducing puberty, estimating economic gain of harvesting mammals, utilizing a time interval of inducing puberty and harvesting mammals that results in a net economic gain and harvesting mammals at the end of that time interval. It is unclear as to how the statement in the specification of "...hence increased biological efficiency" provides support for the claimed methods of managing mammals in which only the costs/gains of inducing puberty and harvesting animals are evaluated in order to obtain a time interval for harvesting animals to yield a net economic gain.

Applicants state that they anticipate augmenting their points by filing a supplemental affidavit. However, a supplemental affidavit has not been received by the Office.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-43 and 45-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of managing bovine wherein the methods comprise inseminating a female bovine with an insemination sample having a plurality of spermatozoa wherein the spermatozoa have been purified to the extent that up to 90% of the spermatozoa have X-bearing and while the prior art (Buchanan 2000) has enabled methods of managing equine by producing equine offspring wherein the methods comprise inseminating a female equine with an insemination sample having a plurality of spermatozoa wherein up to 90% of the spermatozoa have an X chromosome, and while the prior art (Rens US Patent No. 5,985,216, issued November 16, 1999) has enabled methods of managing porcine by producing porcine offspring wherein the methods comprise inseminating a female porcine with an insemination sample having a plurality of spermatozoa wherein up to 92% of the spermatozoa have a Y chromosome, does not reasonably provide enablement for methods of managing any "traditionally herd-managed" nonhuman female mammal for increased economic and biological efficiency comprising estimating the economic cost of inducing early puberty, estimating the economic gain of harvesting bred mammals, determining a time interval that begins with inducing early puberty and ends with harvesting wherein the time interval results in a net economic gain, inducing early puberty in said any nonhuman female mammal, fertilizing at least one egg derived from the female mammal using sex-sorted spermatozoa, producing offspring, and harvesting substantially all of the bred nonhuman female mammals upon the expiration of the determined time interval. The specification does not enable any person skilled in

the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in formulating this rejection (*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

The claims are drawn broadly to methods of managing a plurality of nonhuman traditionally herd-managed female mammals for increased economic and biological efficiency in a commercial environment. The claims include the steps of inducing early puberty in the mammal, fertilizing the mammal with sex-sorted spermatozoa, producing offspring and harvesting said mammals. The claims further comprise estimating the economic cost of inducing early puberty and the economic gain of harvesting mammals and determining a time interval that begins with inducing early puberty and ends with harvesting mammals wherein the time interval results in a net economic gain. Additionally, the claims encompass the use of sex-sorted spermatozoa samples that include at least 90% of spermatozoa that have the same sex determination characteristic.

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re*

*Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(l)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". In the instant case, specification has not adequately taught one of skill in the art how to practice methods of enriching spermatozoa to purities of 100% in bovine mammals or to purities of 90% or greater in all animals for the following reasons.

The claims are inclusive of methods for managing any nonhuman traditionally herd-managed female mammals. However, the specification does not clearly define what is intended to be encompassed by the group of any nonhuman traditionally herd-managed female mammal. The specification at page 6 states that the claimed invention is not intended to be limited to bovine animals and that the claimed invention is applicable "to a variety of species of mammal including, but not limited to, bovids, equids, ovids, canids, goats or swine, as well as less commonly known animals such as elephants, zebra, camels, or kudu...As such, the examples provided are not intended to limit the description of the invention to the management of any particular specie(s) of mammal(s)." In the absence of a disclosure in the specification as to what is intended to be encompassed by traditionally herd-managed mammals, it is unclear as to how one would evaluate whether a mammal constitutes a traditionally herd managed mammal. For instance, it is unclear as to whether such an evaluation would take into

consideration only mammals that are herd managed in the U.S. or would also take into consideration any mammal that is herd managed in any other country or culture. It is unclear as to whether the claims refer to traditional herd management with respect to the fact that the animals are managed for commercial breeding and harvesting purposes or with respect to the fact that the mammals are traditionally considered to be members of a herd. Given the lack of disclosure of what constitutes a nonhuman traditionally herd-managed female mammal and the teachings in the originally filed specification that the methods are intended to be applicable to essentially all mammals, it has been interpreted that at minimum the claims encompass the management of a diverse group of mammals that includes bovine, equine, goat, pigs, as well as other herd mammals such as elephants, deer, zebra and antelope. Accordingly, the claims are intended to include the management of any of these nonhuman female mammal population by inducing early puberty, fertilizing at least one egg of the mammal with sex-sorted sperm, producing offspring and harvesting the female mammals that were used for breeding. The single-calf heifer system is known in the art. However, this system of harvesting each mammal that was used for reproductive purposes is not known in the art as a means for managing diverse populations of nonhuman mammal populations. The teachings in the specification are directed specifically to the management of bovine. The specification does not provide any specific teachings of how to apply the claimed integrated herd management system to any nonhuman mammal.

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In particular, Applicants have not adequately taught how to induce early puberty in any nonhuman traditionally bred female mammal. While the specification states that "Diet is an effective tool to induce puberty" (see page 2), it is not clear as to whether this statement is intended to refer only to bovines. There are no teachings in the specification as to the use of controlling diet as a means of inducing early puberty in other types of female mammals. The specification does not teach that the methods used for inducing early puberty in bovine are also applicable to inducing early puberty in equine, ovine, porcine, goats, elephants, zebra etc. The specification does not exemplify inducing early puberty in non-bovine animals. In the absence of any specific guidance from the specification as to how one would induce early puberty in additional species of mammals then use this female effectively for reproductive purposes, undue experimentation would be required to practice this aspect of the claimed invention.

Secondly, the specification does not provide sufficient guidance as to how to apply the claimed method to the management of any nonhuman female mammal for increased economic and biological efficiency. The specification (e.g., page 12) teaches that the claimed system is applicable to a variety of species of mammal "that can be managed in a similar fashion." However, the claims broadly encompass the use of any "traditionally herd-managed" nonhuman mammal and are not limited to mammals that are conventionally managed in a system in which each animal used for breeding is slaughtered after the birth of their offspring. For example, equine are not typically managed in a replacement system in which the equine that was just bred is replaced with its offspring. Similarly, it is not conventional to manage other herd mammals such

elephants, zebras, whales, etc, in a system in which each time a female mammal gives birth to an offspring, the parent female mammal is slaughtered. The specification does not provide sufficient guidance to enable one skilled in the art to effectively manage such mammals in a manner that would allow for inducing early puberty and harvesting the animals at a time interval that results in a net economic gain and biological efficiency. The specification does not define what is intended to be encompassed by "biological efficiency" within the parameters of a method for managing mammals. At page 2, the specification refers to a "body condition score, hence increased biological efficiency" in relation to bovine animals. However, the specification does not provide guidance as to how to evaluate an increased biological efficiency with respect to non-bovine mammals. Further, Applicants have not established that, for a representative number of species encompassed by the claimed invention, a time interval between inducing early puberty and harvesting the mammals does in fact exist whereby the time interval results in a net economic gain and a net biological gain.

The teachings in the specification support the unpredictability of determining a time interval that results in net economic gain and net biological gain. For example, the specification (page 50) teaches that the IS was not more profitable than traditional management systems of non-replacement heifers. Only by using a simulation in which pregnancy rates were 58% and calf survival was increased, did the IS system become more economically valuable than the TMS. Based on the teachings in the specification, it is unclear as to whether calf survival rates could be increased to those used in the simulation under the conditions set forth in the claims in which the calves are obtained

from mothers in which early puberty was induced and in which fertilization was performed using sex-sorted sperm. Importantly, the specification at page 51 concludes that "The simulations (Table 18) showed that under the assumptions, the IS can be profitable above the TMS. The most appropriate figures to assess the system are those associated with 80% pregnancy rate. This rate is the most acceptable pregnancy rate and could probably be achieve(d) with the IS with further development and research into the project." Accordingly, in the absence of specific guidance as to the criteria that could be used to determine the biological cost and gain of inducing early puberty and harvesting any nonhuman female mammal and in view of the unpredictability in obtaining the required pregnancy and offspring survival rates, undue experimentation would be required for the skilled artisan to practice the claimed method of managing a plurality of any nonhuman female mammal for increased economic and biological efficiency.

Additionally, the ability to sort sperm from any nonhuman mammal on the basis of a sex determination characteristic such that the resulting sample can be used for fertilization to reproducibly generate offspring in which 90% or more of the offspring are female is highly unpredictable. This unpredictability is exemplified by the results set forth in the specification. In particular, pages 40-41 of the specification states:

"Eleven of 16 (69%) calves conceived from semen sorted for X-chromosome were female and all three calves conceived from non-sexed semen were bulls (100%), whereas the only female born to natural serve was female (100%). Seidel et al. (87) reported that 86% of calves conceived from sexed semen are of the desired sex. The result of this data set of 69% of calves conceived from sexed semen were of desired sex, is not an adequate replication of their study as too few individuals were used. The

low percent of desired sex was not expected as the true percent of X-chromosome sperm varied from 86-92% for the batches of semen used in the study."

The specification does not provide any examples in which spermatozoa were sorted to rates above 86-92% and fails to teach how the methodology set forth within the specification could be modified to achieve the production of animals in which more than 69% of the animals of one "desired" sex. The prior art of Rens (US Patent 5,985216, issued 1999) does teach that bovine sperm can be sorted to purities of about 90%. Rens also teaches that under some conditions, porcine sperm could be sorted to a purity of 92% for sperm bearing the Y chromosome. In addition, Buchanan (April 2000, page 1337) teaches methods for sorting equine sperm wherein the sperm were successfully sorted to a purity of 90% for sperm bearing the X chromosome and to 84% for sperm bearing the Y chromosome. However, there is no specific guidance provided in the specification for how one may accomplish the sexing of sperm to achieve purity rates of 95%, 99% or 100% in bovine, equine, ovine, porcine and goats. It is unpredictable as to whether one of skill in the art could sort sperm from these mammals at purity rates of above 90% and generate populations of mammals in which 90% or more of the offspring are female. The unpredictability of sorting sperm to high levels of purity, including purity levels above 90% is supported by the teachings in the art. For example, Fugger (1999; cited in the IDS of 6/12/01) teach that using the most current techniques, human sperm cells can be separated to provide samples containing on average 88% enrichment for X-bearing sperm and 69% enrichment for Y-bearing sperm (see page 1439). Fugger goes on to state that :

"Human sperm cells present unique characteristics that affect the ability to detect and separate X and Y sperm by flow cytometry. The current flow technology appears to be most efficient with sperm cells that have a substantial difference in total DNA, are relatively homogeneous with respect to physical shape and cellular morphology, and are more paddle shaped to take advantage of flow-induced orientation before fluorescence detection. Most human sperm, however, are heterogeneous, vary substantially within and between individuals, are oval in shape, vary in the magnitude of difference in DNA content between X and Y chromosomes due to individual variation in size of the Y chromosome, and contain a relatively small 2.8% difference in total DNA content compared to >3.5% for most domestic animals."

Additionally, Johnson (1992, page 13; cited in the IDS of 6/12/01) teach the difference in DNA content between X and y chromosome bearing sperm for several organisms, including turkey (0% difference), human (2.9% difference) and rabbit (3% difference). Johnson also reports that rabbit sperm were sorted to purities of 86% for X-chromosome bearing sperm and 81% for Y-chromosome bearing sperm.

However, there are no teachings in the prior art as to how to overcome the problems associated with a lack of difference in the DNA content between X and Y-chromosome bearing sperm or the challenges imposed by the shape, morphology and heterogeneity of sperm. The specification and prior art do not appear to exemplify any methods in which sperm from are reproducibly purified to sufficient purity to generate populations of mammals comprising at least 90% of female offspring. The specification does not provide sufficient guidance as to how to sort sperm from equine, ovine and

goats to purity levels of above 90%. It is unpredictable as to what methodologies should be employed to achieve these high purity levels and to produce offspring in which 90% or more of the offspring are female.

Accordingly, in view of the unpredictability in the art and the lack of specific guidance provided in the specification, undue experimentation would be required to practice the invention as it is broadly claimed.

**RESPONSE TO ARGUMENTS:**

**RESPONSE TO ARGUMENTS:**

In the response of December 15, 2004, Applicants traversed the above rejection. Applicants arguments have been fully considered but are not persuasive to overcome the present grounds of rejection. Each of Applicants arguments are addressed below.

Applicants state that broad concepts relating to operating a herd management system are disclosed in the specification and the specific examples relating to bovine are merely an example of the operation of the system. It is stated that all aspects of the invention are applicable to any traditionally herd-managed mammal. Applicants state that examples of using diet to induce puberty in bovine are taught in the specification and conclude that the statement in the specification that "diet is an effective tool to induce puberty" enables the full scope of the claimed invention. However, Applicants have not established that diet can be used to induce early puberty in any mammal other than bovine. There is no evidence provided in the specification, no art cited, and no scientific arguments presented to support the conclusion that diet can be used to induce early puberty in the wide range of mammals encompassed by any "traditionally herd-

managed" mammal. The specification has not established that without undue experimentation one of skill in the art can induce early puberty in other mammals by altering their diet. While the diets used to induce early puberty in bovine are provided in the specification and in the prior art, the specification does not teach that these diets can be used to induce early puberty in equine, goats, porcine, elephants, zebra etc. If alternative diets are required for non-bovine mammals, there is no specific guidance provided in the specification as to how to select such diets in order to reproducibly induce early puberty. Additionally, the claims are not limited to methods for inducing early puberty by altering the mammals diet. Applicants state that a considerable amount of experimentation is permissible if the experimentation is routine. However, Applicants have not established that the experimentation required to induce early puberty in any traditionally herd-managed mammal is routine. The specification does not teach which parameters of diet or other unspecified methodologies or agents could be routinely analyzed in order to reasonably identify other means for inducing early puberty. For the experimentation to be routine, one must know which parameters are to be analyzed and the potential effect of such parameters. The statement in the specification that puberty has been induced in bovine by altering their diet does not provide sufficient guidance and teachings to support the conclusion that identifying diets and other agents that induce early puberty in a wide variety of mammals is a matter of routine experimentation.

Applicants argue that the specification provides explanations as to why the pregnancy rates and calf survival rates were low and that all of the factors that account

for the fact that the simulated management systems did not result in an increased economic efficiency "can be adjusted for by simulation to achieve the desired results." However, the claimed method is not one for performing a computer simulation, but rather an actual management system with live animals. Applicants have not established that the simulations can in fact be performed with any group of traditionally herd-managed female mammals to provide a system for increased economic and biological efficiency. Applicants state that they intend to file a declaration establishing the "significant degree of difficulty associated with obtaining a full herd of animals upon which to demonstrate the operation of herd management techniques...It is anticipated that the affidavit will further state that the difficulties in obtaining a herd of animals, combined with the limited resources often available to those engaged in academic and scientific pursuits, frequently results in a situation where persons wishing to study herd management practices must do so pragmatically based on animals, facilities, and conditions as may be readily available." However, the affidavit referred to in the response of December 15, 2004 has not been received by the office. Further, it is unclear as to how such an affidavit would provide support for the enablement of the full scope of the claimed invention. By stating the difficulties that one would encounter in trying to establish that the claimed herd management system can be performed, Applicants do not establish that the skilled artisan could practice such methods. Rather, such statements support the unpredictability that the artisan could practice the claimed invention and could use the claimed management system for increased economic and biological efficiency with any traditionally herd-managed mammal. The response does

not explain why the skilled artisan would be able to practice the full scope of the claimed invention if Applicants themselves are unable to practice the claimed invention with bovine.

Applicants further traverse the rejection by stating that they are enabling for the full scope of the claimed invention as it encompasses methods of sex sorting to purities of 90% and above. Applicants state that the accuracy of sex-sorting sperm can be improved by adjusting the parameters of the flow cytometer. However, Applicants' allegations of improved methods for sex-sorting sperm are not supported by any factual evidence. Applicants have not established that others in the art, following the teachings in the specification and prior art, have been able to achieve sex-sorting purities of above 90% for any traditionally herd-managed mammal by adjusting the parameters of the flow cytometer. Applicants provide statements of what experimentation could be performed to try to increase the accuracy of sex-sorting sperm but do not provide any evidence to establish that such methodologies are effective and can be employed without undue experimentation. It is argued that Fugger is concerned only with sorting human sperm and that the findings obtained with human sperm do not apply to the present claims which are directed to non-human sperm. It is also argued that the findings of Johnson apply only to turkey, human and rabbit sperm and that these are not traditionally herd-managed mammals. However, Applicants have not established that the difficulties associated with sex-sorting human, turkey and rabbit sperm are not applicable to the sperm of the diverse group of mammals encompassed by the present claims. The claims encompass sex-sorting the sperm of any "traditionally herd-managed"

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female mammal" and this group of mammals is considered to include a wide variety of mammals whose sperm properties are not defined in the specification or prior art. It has not been established that a reasonable number of mammals within this group have a sufficient difference in the DNA content of their X and Y chromosome bearing sperm so as to allow for the effective sorting of sperm from these mammals to purities that result in "at least 90%" female offspring (i.e., purities that result in 90, 91, 92, 93, 94, 95, 96, 97, 98, 99 and 100% female offspring). Applicants state that the results disclosed in the specification for bovine were due to a low number of individual animals used and that given that Seidel achieved 86% pregnancy rates when using a greater number of animals, one would expect that higher pregnancy rates could be achieved. However, the fact that 86% pregnancy rates were achieved with bovine does not establish that the skilled artisan can practice, without undue experimentation, a method of managing mammals in which from 90 to 100% of the mammals produced are female. The teachings in the specification and prior art do not lead to the conclusion that it is predictable and a matter of routine experimentation to perform methods of sex-sorting sperm at accuracies which allow for the production of populations consisting of 90-100% female mammals and that this methodology is routinely applicable to all traditionally herd-managed mammals.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-43 and 45-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 28-43 and 45-50 are indefinite over the recitation of "biological efficiency." This phrase is not clearly defined in the specification and there is no art recognized definition for these phrases as they apply to bovine, equine, ovine, porcine, goats or all "traditionally herd-managed" mammals. It is unclear as to what parameters are to be evaluated in order to determine that management of any traditionally herd-managed mammal is "biologically efficient." In the absence of a complete and clear definition as to what is intended to be encompassed by this phrase, one of skill in the art cannot determine the meets and bounds of the claimed invention.

#### **RESPONSE TO ARGUMENTS:**

In the response of December 15, 2004, Applicants traverse this rejection by pointing to page 2 of the specification "where the term is expressly stated and defined in terms of a greater proportion of total feed used for weight production and a smaller amount of feed used for maintenance, lactation, gestation, and body score as the cow herd becomes younger." However, in fact, page 2 of the specification does not provide such a definition for the phrase "biological efficiency." Rather, page 2 states "it has been hypothesized that the younger the cow herd, the greater proportion of total feed used for weight production and a smaller amount of feed used for maintenance, lactation, gestation, and body condition score, hence increased biological efficiency." This statement in the specification would not lead one to conclude that the phrase "biological

efficiency" is intended to be limited to and defined as any system in which there is a greater amount of feed used for weight production and a smaller amount used for maintenance of cow herds or any system in which there is a younger cow herd. The phrase "hence increased biological efficiency" is present at the end of the sentence, but it is unclear as to how this phrase relates to the remainder of the sentence. Even if one were to read this as an example of what might be encompassed by biological efficiency, such a statement does not provide a complete definition for the phrase "biological efficiency" – rather the statement provides only an example of what might be encompassed by "biological efficiency" as the phrase relates to bovine management systems.

B. Claims 28-43 and 45-50 are indefinite over the recitation of "traditionally herd-managed female mammals." This phrase is not specifically defined in the specification and there is no art recognized definition for this phrase. What constitutes a traditionally herd-managed female mammal is subjective and varies over time, with country and culture. It is unclear as to what mammals are intended to be encompassed by this phrase and thereby one of skill in the art could not determine the meets and bounds of the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach

the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Carla Myers  
March 1, 2005

*Carla Myers*  
CARLA J. MYERS  
PRIMARY EXAMINER